

AMENDMENTS TO THE CLAIMS

This listing of the claims replaces all prior versions and listings of the claims for this application. Within this listing of the claims, claim 1 has been amended; no other changes have been made. Deletions to claim language is indicated with a simple strikethrough and additions to the claim language are underlined in bold.

1. **(Currently amended)** An erodible, gastric-retentive drug dosage form for administering a pharmacologically active agent to the stomach, duodenum, and upper small intestine of a patient, the dosage form comprising the pharmacologically active agent incorporated in a matrix of at least one biocompatible, hydrophilic polymer that (a) swells in the presence of water in gastric fluid such that the size of the dosage form is sufficiently increased to provide gastric retention in the stomach of a patient in whom the fed mode has been induced, (b) gradually ~~erode~~ erodes within the gastrointestinal tract over a determinable time period, and (c) ~~release~~ releases the active agent throughout the determinable time period, wherein the dosage form is optimized by subjecting the dosage form to a disintegration test for an extended period of time such that the dosage form has an *in vitro* active agent release profile that correlates to a desired *in vivo* active agent release profile for the dosage form.
2. **(Original)** The dosage form of claim 1, wherein a first fraction of the active agent is released from the dosage form by diffusing out of the polymer matrix as a result of (a) and a second fraction of the active agent is released from the dosage form by erosion of the polymer matrix during (b).
3. **(Original)** The dosage form of claim 2, wherein the second fraction is greater than the first fraction.
4. **(Original)** The dosage form of claim 3, wherein at least 75 wt.% of the active agent is released within the determinable time period.
5. **(Original)** The dosage form of claim 4, wherein at least 85 wt.% of the active agent is released within the determinable time period.
6. **(Original)** The dosage form of claim 1, wherein the at least one biocompatible hydrophilic polymer is selected from the group consisting of: polyalkylene oxides; cellulosic polymers; acrylic acid

and methacrylic acid polymers, and esters thereof; maleic anhydride polymers; polymaleic acid; poly(acrylamides); poly(olefinic alcohol)s; poly(N-vinyl lactams); polyols; polyoxyethylated saccharides; polyoxazolines; polyvinylamines; polyvinylacetates; polyimines; starch and starch-based polymers; polyurethane hydrogels; chitosan; polysaccharide gums; zein; shellac-based polymers; and copolymers and mixtures thereof.

7. **(Original)** The dosage form of claim 6, wherein the at least one biocompatible hydrophilic polymer is a polyalkylene oxide polymer or copolymer, a cellulosic polymer, a gum, or a mixture thereof.

8. **(Original)** The dosage form of claim 7, wherein the at least one biocompatible hydrophilic polymer is a polyalkylene oxide selected from the group consisting of poly(ethylene oxide), poly(ethylene oxide-co-propylene oxide), and mixtures thereof.

9. **(Original)** The dosage form of claim 8, wherein the at least one biocompatible hydrophilic polymer is poly(ethylene oxide) optionally in admixture with poly(ethylene oxide-co-propylene oxide).

10. **(Original)** The dosage form of claim 6, wherein the at least one biocompatible hydrophilic polymer is a cellulosic polymer selected from the group consisting of hydroxymethylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropyl methylcellulose, carboxymethylcellulose, and mixtures thereof.

11. **(Original)** The dosage form of claim 6, wherein the at least one biocompatible hydrophilic polymer is xanthan gum.

12. **(Original)** The dosage form of claim 1, wherein the at least one biocompatible hydrophilic polymer has a number average molecular weight in the range of approximately 5,000 and 20,000,000.

13. **(Original)** The dosage form of claim 1, wherein the weight ratio of the active agent to the biocompatible hydrophilic polymer is in the range of about 1:500 to about 85:15.

14. **(Original)** The dosage form of claim 13, wherein the weight ratio of the active agent to the biocompatible hydrophilic polymer is in the range of about 5:95 to about 80:20.

15. **(Original)** The dosage form of claim 14, wherein the weight ratio of the active agent to the biocompatible hydrophilic polymer is in the range of about 30:70 to about 80:20.

16. **(Original)** The dosage form of claim 15, wherein the weight ratio of the active agent to the biocompatible hydrophilic polymer is in the range of about 30:70 to about 70:30.

17. **(Original)** The dosage form of claim 1, wherein at least one of the biocompatible hydrophilic polymers is crosslinked.

18. **(Original)** The dosage form of claim 1, wherein the active agent has an aqueous solubility of less than about 25 wt.% at 20°C.

19. **(Original)** The dosage form of claim 18, wherein the active agent has an aqueous solubility of less than about 10 wt.% at 20°C.

20. **(Original)** The dosage form of claim 19, wherein the active agent has an aqueous solubility of less than about 5 wt.% at 20°C.

21. **(Original)** The dosage form of claim 1, wherein the active agent has a molecular weight greater than 300 daltons.

22. **(Original)** The dosage form of claim 18, wherein the at least one biocompatible hydrophilic polymer has a number average molecular weight in the range of about 10,000 to 8,000,000.

23. **(Original)** The dosage form of claim 18, wherein the active agent is selected from the group consisting of topiramate, nifedipine, acyclovir, alprazolam, phenytoin, carbamazepine, ranitidine, cimetidine, famotidine, clozapine, nizatidine, omeprazole, gemfibrozil, lovastatin, nitrofurantoin, losartan, docetaxel and paclitaxel.

24. **(Original)** The dosage form of claim 23, wherein the active agent is topiramate.

25. **(Original)** The dosage form of claim 23, wherein the active agent is paclitaxel.

26. **(Original)** The dosage form of claim 18, wherein the active agent is a *Helicobacter pylori* eradicant.

27. **(Original)** The dosage form of claim 26, wherein said eradicant is selected from the group consisting of bismuth subsalicylate, bismuth citrate, amoxicillin, tetracycline, minocycline, doxycycline, clarithromycin, thiampenicol, metronidazole, omeprazole, ranitidine, cimetidine, famotidine and combinations thereof.

28. **(Original)** The dosage form of claim 27, wherein said eradicant is bismuth subsalicylate.

29. **(Original)** The dosage form of claim 1, wherein the active agent is contained within a vesicle.

30. **(Original)** The dosage form of claim 29, wherein the active agent is water soluble but rendered sparingly water soluble by the vesicle.

31. **(Original)** The dosage form of claim 30, wherein the vesicle is selected from the group consisting of liposomes, nanoparticles, proteinoid and amino acid microspheres, and pharmacosomes.

32. **(Original)** The dosage form of claim 31, wherein the vesicle is comprised of a nanoparticle.

33. **(Original)** The dosage form of claim 32, wherein the nanoparticle is a nanosphere, a nanocrystal, or a nanocapsule.

34. **(Original)** The dosage form of claim 30, wherein the active agent is selected from the group consisting of metformin hydrochloride, vancomycin hydrochloride, captopril, erythromycin lactobionate, ranitidine hydrochloride, sertraline hydrochloride, ticlopidine hydrochloride, amoxicillin, cefuroxime axetil, cefaclor, clindamycin, doxifluridine, tramadol, fluoxetine hydrochloride, ciprofloxacin hydrochloride, ganciclovir, bupropion, lisinopril, minocycline, doxycycline, and esters of ampicillin.

35. **(Original)** The dosage form of claim 34, wherein the active agent is metformin hydrochloride.

36. **(Original)** The dosage form of claim 34, wherein the active agent is ciprofloxacin hydrochloride.

37. **(Original)** The dosage form of claim 1, wherein the active agent is enterically coated.

38. **(Canceled)**

39. **(Original)** The dosage form of claim 1, wherein the dosage form is comprised of a tablet.

40. **(Original)** The dosage form of claim 1, wherein the dosage form is comprised of a capsule.

41-44. **(Canceled)**

45. **(Previously presented)** The dosage form of claim 1, wherein the correlation between the *in vitro* active agent release profile and the *in vivo* active agent release profile is the same.

46. **(Previously presented)** The dosage form of claim 1, wherein the correlation between the *in vitro* active agent release profile and the *in vivo* active agent release profile is linear or substantially linear such that the ratio of *in vivo* disintegration to *in vitro* disintegration is constant or substantially constant.

47. **(Previously presented)** The dosage form of claim 1, wherein the disintegration test is conducted using USP disintegration test equipment.

48. **(Previously presented)** The dosage form of claim 1, wherein the dosage form is optimized by increasing particle size of the active agent.

49. **(Previously presented)** The dosage form of claim 1, wherein the dosage form is optimized by selecting a polymer that erodes faster than it swells.

50. **(Previously presented)** An erodible, gastric-retentive drug dosage form for administering a pharmacologically active agent to the stomach, duodenum, and upper small intestine of a patient, the dosage form comprising the pharmacologically active agent incorporated in a matrix of at least two polyalkylene oxide polymers or copolymers that (a) swell in the presence of water in gastric fluid such

that the size of the dosage form is sufficiently increased to provide gastric retention in the stomach of a patient in whom the fed mode has been induced, (b) gradually erode within the gastrointestinal tract over a determinable time period, and (c) release the active agent throughout the determinable time period, wherein the dosage form is formulated so as to provide an active agent release profile *in vivo* that corresponds to a desired active agent release profile obtained for the dosage form *in vitro* using USP disintegration test equipment, and further wherein one of the at least two polyalkylene oxide polymers or copolymers has a number average molecular weight of 2,000,000 or greater and the other of the at least two polyethylene oxide polymers has a number average molecular weight below 2,000,000.

51. **(Previously presented)** The dosage form of claim 50, wherein one of the at least two poly(ethylene oxide) polymers has a number average molecular weight in the range of approximately 200,000 and the other poly(ethylene oxide) polymer has a number average molecular weight in the range of approximately 2,000,000.

52. **(Previously presented)** The dosage form of claim 51, further comprising a third poly(ethylene oxide) polymer having a number average molecular weight in the range of about 7,000,000.

53. **(Previously presented)** An erodible, gastric-retentive drug dosage form for administering a pharmacologically active agent to the stomach, duodenum, and upper small intestine of a patient, the dosage form comprising the pharmacologically active agent incorporated in a matrix of at least one polyalkylene oxide polymer that (a) swells in the presence of water in gastric fluid such that the size of the dosage form is sufficiently increased to provide gastric retention in the stomach of a patient in whom the fed mode has been induced, (b) gradually erodes within the gastrointestinal tract over a determinable time period, and (c) releases the active agent throughout the determinable time period, wherein the dosage form is formulated so as to provide an active agent release profile *in vivo* that corresponds to a desired active agent release profile obtained for the dosage form *in vitro* using USP disintegration test equipment, and further wherein the at least one polyalkylene oxide polymer has a number average molecular weight ranging from about 5000 to less than 900,000.

54. **(Previously presented)** An erodible, gastric-retentive drug dosage form for administering a pharmacologically active agent to the stomach, duodenum, and upper small intestine of a patient, the dosage form comprising the pharmacologically active agent incorporated in a matrix of poly(ethylene oxide) admixed with poly(ethylene oxide-co-propylene oxide), wherein the matrix (a) swells in the

presence of water in gastric fluid such that the size of the dosage form is sufficiently increased to provide gastric retention in the stomach of a patient in whom the fed mode has been induced, (b) gradually erodes within the gastrointestinal tract over a determinable time period, and (c) releases the active agent throughout the determinable time period, and further wherein the dosage form is formulated so as to provide an active agent release profile *in vivo* that corresponds to a desired active agent release profile obtained for the dosage form *in vitro* using USP disintegration test equipment.